Rebekah Conroy (rconroy@stoneconroy.com)
STONE CONROY LLC
25A Hanover Road, Suite 301
Florham Park, NJ 07932
Tel.: (973) 400-4181

Of Counsel:
Jake M. Holdreith (jholdreith@robinskaplan.com)
Christopher A. Pinahs (cpinahs@robinskaplan.com)
Samuel J. LaRoque, Ph.D. (slaroque@robinskaplan.com)
ROBINS KAPLAN LLP
800 LaSalle Ave, Suite 2800
Minneapolis, MN 55402
Tel.: (612) 349-8500

Oren D. Langer (olanger@robinskaplan.com)
ROBINS KAPLAN LLP
1325 Avenue of the Americas, Suite 2601
New York, NY 10019
Tel.: (212) 980-7400

Attorneys for Defendants Amneal Pharmaceuticals of New York, LLC and Amneal EU, Limited

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SALIX PHARMACEUTICALS, INC., SALIX PHARMACEUTICALS, LTD., ALFASIGMA S.P.A. and BAUSCH HEALTH IRELAND LTD., Plaintiffs, v. AMNEAL PHARMACEUTICALS OF NEW YORK, LLC, and AMNEAL EU, LIMITED, Defendants.	Case No.: 1:24-cv-04607-ESK-AMD *Document Filed Electronically*

RESPONSE OF DEFENDANTS AMNEAL PHARMACEUTICALS OF NEW YORK, LLC, AND AMNEAL EU, LIMITED TO PLAINITFFS' MOTION TO CONSOLIDATE

PRELIMINARY STATEMENT

Defendants Do Not Oppose Consolidation Provided There Is No Prejudicial Delay To Resolution Of This Case.

On November 27, 2024, Plaintiffs filed a motion to consolidate this case ("*Amneal* action") with four pending actions in this court because all of the actions involve patent infringement allegations arising out of each defendants' submission of Abbreviated New Drug Applications ("ANDAs") for generic versions of Xifaxan® (rifaximin) tablets: Case No. 3:24-cv-07140-ESK-AMD ("*Norwich II* action"); Case No. 1:24-cv-09512-ESK-AMD ("*Zydus* action"); 1:24-cv-10213-ESK-AMD ("*Cipla* action"); and 1:24-cv-10356-ESK-AMD ("*Carnegie* action"). Dkt. 66-1.

Amneal Pharmaceuticals of New York, LLC and Amneal EU, Limited (together "Amneal") do not oppose the motion to consolidate, ***provided that any consolidation is not used to prejudicially delay the overall schedule or resolution of Amneal's case beyond the schedule proposed by Amneal***. As Plaintiffs' memorandum in support of its motion indicates, the *Amneal* action was the first filed of the actions sought to be consolidated and the approval of Amneal's ANDA product is subject to a 30-month statutory stay that expires **August 29, 2026**. *See* Dkt. 66-1 at 3. Amneal will thus be prejudiced if consolidation delays resolution of Amneal's case, either beyond the 30-month stay, or beyond the date of final resolution of Amneal's case without consolidation.

As the Court may recall, Plaintiffs previously opposed consolidation with the *Norwich II* action when Amneal raised the issue earlier in these proceedings. *See* Dkt. 39 at 7-8. Thus, given Plaintiffs' strategic flip-flop as to the merits of consolidation, and to the extent Plaintiffs now seek to consolidate the cases to create delay in final resolution of the *Amneal* action, Amneal objects to consolidation. Consolidation should only be ordered if a case schedule preserves obtaining a final

resolution before expiration of the 30-month stay date in this action. is proposed by the parties and adopted by the Court. Therefore, Amneal agrees to consolidation only if this case can proceed to trial no later than March 2026 in accordance with the proposed consolidated schedule below.

Background

I. Plaintiffs filed actions against ANDA filers in bad faith even though related patents have already been found invalid.

Plaintiffs filed their patent infringement action against Amneal after Amneal submitted an ANDA containing a Paragraph IV Certification notice to the U.S. Food and Drug Administration ("FDA") seeking approval to sell generic versions of Xifaxan® (rifaximin) tablets. Plaintiffs asserted seven patents against Amneal allegedly covering its Xifaxan® product; five patents are related to rifaximin polymorphs (patents specifically related to the "delta" and "epsilon" polymorphs are asserted in the *Amneal* case), and two patents are related to using rifaximin to treat various forms of irritable bowel syndrome (IBS) in females. *See* Dkt. 23; Dkt. 39 at 2-3. However, related patents of the asserted patents in this case both regarding (i) rifaximin polymorphs and (ii) using rifaximin to treat various forms of IBS in patients (which includes females) have already been found invalid as obvious in a different litigation. *Salix Pharms. Ltd. v. Norwich Pharms. Inc.*, 2022 WL 3225381, *6-*8, *18-*22 (D. Del. Aug. 10, 2022), *aff'd* 98 F.4th 1056, 1060-1067 (Fed. Cir. 2024) ("*Norwich I*"). Plaintiffs' entire case should ultimately fail due to collateral estoppel given the previous findings regarding invalidity/obviousness in the *Norwich I* litigation. *See id.*; Dkt. 24 ¶¶ 47-58, 204; Dkt. 39 at 3; Dkt. 54. Moreover, the commercial Xifaxan® product consists primarily of "alpha" polymorph, not "delta" or "epsilon" polymorphs. Dkt. 24 ¶¶14, 41, 60. Thus Amneal has asserted that Plaintiffs' case not only fails for multiple reasons (invalidity and non-infringement), but also that Plaintiffs' actions in listing asserted patents in the Orange Book and

filing suit against ANDA filers based thereon should also subject Plaintiffs to delisting, unlawful monopolization, and sham litigation antitrust liability. *See* Dkt. 24; Dkt 39 at 3.

Since filing the *Amneal* action, Plaintiffs have also filed actions in this court against Norwich, Zydus, Cipla, and Carnegie, each of which have also filed ANDAs to sell generic rifaximin tablets. *See* Dkt. 66-1 at 1-5. Plaintiffs have asserted infringement of the same two patents regarding using rifaximin to treat IBS that it asserted in the *Amneal* action in each of those actions. *See id.* at 2 ("All five cases assert infringement of U.S. Patent Nos. 11, 779, 571 ("'571 patent") and 11,564,912 ("'912 patent")"). One of the "polymorph" patents is also asserted in three of the other actions filed since the *Amneal* action was filed. *See id.* at 3 n.4 ("four of [the five] actions also involv[e] the '196 patent"). Answers have not yet been filed in any of the other actions. *See id.* at 4-5. Norwich has requested permission to file a motion to dismiss, or in the alternative to transfer to Delaware, the jurisdiction where related patents of Plaintiffs were already found invalid in the *Norwich I* litigation. *See id.* at 4.

II. Amneal has consistently sought an expeditious case schedule to resolve this action before expiration of the statutory stay.

Because of the statutory stay expiring August 29, 2026,[1] Amneal previously requested that the case be scheduled so that trial occurs in January 2026; Daubert and other pretrial filings and

[1] The Hatch-Waxman Act (21 U.S.C. § 301, et seq.) sets forth special procedures for identifying, and resolving, patent disputes related to pharmaceuticals.

> It requires the brand-name manufacturer to list in its New Drug Application the "number and the expiration date" of any relevant patent. See 21 U.S.C. § 355(b)(1). And it requires the generic manufacturer in its Abbreviated New Drug Application to "assure the FDA" that the generic "will not infringe" the brand-name's patents. ... The generic can provide this assurance in one of several ways. See 21 U.S.C. § 355(j)(2)(A)(vii). It can certify that the brand-name manufacturer has not listed any relevant patents. It can certify that any relevant patents have expired. It can request approval to market beginning when any still-in-force patents expire. Or, it can certify that any listed, relevant patent "is invalid or will not be infringed by the manufacture, use, or sale" of the drug described in the Abbreviated New Drug Application. See § 355(j)(2)(A)(vii)(IV). Taking this last-mentioned route (called

hearings all be completed no later than December 2025; all expert discovery including depositions be completed by September 19, 2025; expert report exchanges completed by August 13, 2025, starting June 20, 2025; and fact discovery completed by May 30, 2025. *See* Dkt. 39 at 11-14. The Court has not yet set all case deadlines in the *Amneal* action, but has set a fact discovery deadline to keep the case on track for resolution prior to expiration of the 30-month stay. Dkt. 65. The parties in the *Amneal* action have already served Initial Written Discovery, Invalidity Contentions and attendant document production, Non-Infringement Contentions and attendant document production, Infringement Contentions and attendant document production, Responses to Invalidity Contentions, exchanged submissions regarding claim construction, and recently agreed that it is not necessary for the Court to perform any new claim construction. *See* Dkt. 39 at 12-13; Dkt. 65; Dkt. 69.

Amneal initially raised the issue of potential consolidation with the *Norwich II* action when the parties discussed scheduling for this matter prior to the Rule 16 Conference, given the overlapping patent infringement issues in this action and the *Norwich II* action. But Plaintiffs opposed consolidation at that time, and had not even identified the *Norwich II* action as a related case to the *Amneal* action in filing it, thus resulting in it initially being assigned to a different judge. *See* Dkt. 39 at 7-9.

Now, Plaintiffs file a motion to consolidate, making arguments opposite to what they argued in July. *See id.*; *cf.* Dkt. 66-1. Moreover, Plaintiffs did not meet and confer with Amneal

---

> the "paragraph IV" route), automatically counts as patent infringement, see 35 U.S.C. § 271(e)(2)(A) (2006 ed., Supp. V), and often "means provoking litigation." ... If the brand-name patentee brings an infringement suit within 45 days, the FDA then must withhold approving the generic, usually for a 30-month period, while the parties litigate patent validity (or infringement) in court.

FTC v. Actavis, Inc., 570 US 136, 143 (2013).

before filing their motion nor even identify before or when filing their motion exactly how Plaintiffs propose the case schedule in any consolidated action should proceed, let alone not identify the position of any of the defendants in the other cases as to consolidation or as to a case schedule for any consolidated action in their motion. It is not even clear if Plaintiffs met and conferred with other defendants regarding such before filing their motion. *See generally* Dkt. 66-1. Plaintiffs certainly did not engage before filing their motion with Amneal in any meet and confer, with or without other defendants, regarding any proposals for how any consolidated cases would proceed and whether any steps in scheduling would be taken to alleviate any prejudice to Amneal or prevent delay in the Amneal action. After receiving Plaintiffs' filed motion, Amneal conferred with Plaintiffs, and some of the other defendants, regarding a schedule for any consolidated action consistent with the Amneal schedule. Plaintiffs proposed a schedule in which the expert discovery phase of the litigation would end in March 2026. Plaintiffs' proposed schedule did not contemplate any final pretrial and trial dates. Plaintiffs' proposed schedule would unduly delay the *Amneal* action because it necessarily contemplates a Summer 2026 trial, at the earliest, and that would not give the Court adequate time to file an opinion in advance of the Amneal 30-month stay deadline.

Argument

I. Consolidation that would delay resolution of the *Amneal* action should not be granted.

> Although a common question of law or fact shared by the cases is a prerequisite for consolidation, the mere existence of common issues does not require consolidation. "Once a common question of law or fact has been established, the decision to consolidate rests in the sound discretion of the district court." The court, in exercising its discretion, "should weigh the interests of judicial economy against the potential for new delays, expense, confusion, or prejudice."

Cima Labs, Inc. v. Actavis Grp. HF, No. 06-1970, 2007 WL 1672229, at *6 (D.N.J. June 7, 2007) (quoting *In re Consol. Parlodel Litig.*, 182 F.R.D. 441, 444 (D.N.J. 1998); other internal citations and quotations omitted). In *Cima*, the Court ordered consolidation for pre-trial purposes, but only after finding that in the ANDA patent infringement cases at issue there, discovery had not advanced in either of the cases such that consolidation would be inefficient or prejudicial to the parties. *Id.* at *8; *see also Smithkline Beecham Corp. v. Geneva Pharms., Inc.*, No. 00-1393, 2001 WL 1249694, at *5 (E.D. Pa. Sept. 26, 2001) (ordering consolidation of ANDA patent infringement cases for pretrial purposes only after finding discovery in the earliest-filed actions is not "so far advanced that pretrial consolidation would be inefficient or prejudicial to the parties"). "Motions to consolidate should be denied where ... it will cause delay in one of the cases, or will lead to ... prejudice in the trial of a case." *McGillvary v. Scutari*, No. 23-22605, 2024 WL 3878749, at *4 (D.N.J. Aug. 20, 2024).

Plaintiffs cite *Eastman Chem. Co. v. AlphaPet Inc.*, No. 09-971, 2011 WL 7121180, at *7 (D. Del. Dec. 29, 2011) in support of the argument that consolidation is appropriate even where there is some difference in the progression of the cases before consolidation. Dkt. 66-1 at 8. But *Eastman Chem.* was not an ANDA patent infringement case (nor was the *Rohm and Haas* case cited in Plaintiffs' brief), and did not consider resolving the matter before the expiration of the 30-month statutory stay, or the prejudice that would result from failure to complete the case before that time. Moreover, the Court found the parties' proposed case schedules for both cases that were to be consolidated were "not dramatically different." 2011 WL 7121180, at *8.

When the statutory 30-month stay for FDA approval of an ANDA elapses, the FDA may approve the ANDA, and the ANDA holder then must decide whether to launch its product "at risk" of a future adverse court decision, including from any preliminary injunction the NDA holder may

file. *See Genentech, Inc. v. Sandoz, Inc.*, Civ. No. 23-4085, 2024 WL 939692, at *5 n.4 (D.N.J. Mar. 5, 2024). This prospect should incentivize everyone involved in the original ANDA litigation "to strive to obtain a final court decision well within the 30-month period." *Id.* In *Roxane Laboratories, Inc. v. Abbott Laboratories*, the court denied a motion to consolidate ANDA litigations that were "at significantly different stages of litigation." 2013 WL 5217571, *3 (S.D. Ohio Sept. 16, 2013). Roxane had opposed consolidation because "there is a substantial difference in trial readiness between [the cases for which the motion to consolidate was made]" and it would "be unavoidably prejudiced because consolidation will delay resolution of all the actions beyond 30 months from the filing of [the original case]." *Id.* The Court explained that since all the cases were before it, it could minimize the risk of inconsistent results and oversee efficient discovery to minimize burden on the Court, but declined to grant any formal consolidation so as not to create delay in the more advanced litigation. *Id.* at *3-*4. The Court was unwilling to grant consolidation where no schedule had been set in the latest action which the patent holder sought to consolidate with other actions that were already in the midst of fact discovery. *Id.*

Similarly, here Plaintiffs seek to consolidate with the *Amneal* action several actions in which no answer has been filed yet and where no case schedule has been set, while significant fact discovery has already occurred in the *Amneal* action and where the parties have agreed that no claim construction by the Court is necessary. *See* Background pp. 2-3, *supra*.[2] Moreover, Plaintiffs

[2] Amneal suggested in July in the parties' Rule 26 Report that consolidation with the *Norwich II* case was appropriate. Dkt. 39 at 8. At the time, only *Amneal* and *Norwich II* had been filed and those cases could have been put together on an expedited schedule. The follow-on ANDA litigations against Zydus, Cipla, and Carnegie were filed months later. *See* Dkt. 66-1 at 4-5. Even back in July, Amneal noted that when determining whether to consolidate, the Court should weigh the interest in judicial convenience against "the potential for delay, confusion, and prejudice caused by consolidation." Dkt. 39 at 8. Since then, Norwich has filed a motion to dismiss/transfer in the *Norwich II* case, which has not progressed in the same manner as *Amneal*.

have not proposed a schedule for a consolidated action that seeks to "obtain a final court decision well within the 30-month period." *Cf. Genentech*, 2024 WL 939692, at *5 n.4.

II. Amneal has no objection to consolidation so long as the schedule allows final judgment to be entered before August 2026.

As detailed above, consolidation should not be granted if consolidation would lead to a consolidated case schedule that will delay progression of the *Amneal* action and is inconsistent with being able reach final resolution of the action before August 2026. However, should all the parties agree to, or the Court set, a case schedule for any consolidated action consistent with the deadlines already set in the *Amneal* action, and that provides for scheduling a trial for early 2026, so post-trial briefing and a court decision and final judgment can be entered before August 2026, then Amneal does not oppose consolidation. The parties to any consolidated action would need to agree to expedited discovery to catch up to the fact discovery already conducted in the *Amneal* action, and agree, like Amneal and Plaintiffs have, that no claim construction by the Court is necessary. The fact discovery deadline in the *Amneal* action is currently set for June 6, 2025. Dkt. 65 at 2. That date could potentially be extended to July 18, 2025, for a consolidated action to allow other parties some additional time to complete fact discovery. Amneal proposes the following case schedule for a consolidated action:[3]

Deadline to seek leave to amend pleadings or to join new parties	January 15, 2025
Deadline for disclosures related to advice of counsel defense (L. Pat. R. 3.8)	Apr 25, 2025
Fact Discovery Deadline	July 18, 2025
Exchange of opening expert reports	Aug 13, 2025
Exchange of rebuttal expert reports	Sept 17, 2025

[3] Counsel for Amneal provided Plaintiffs' counsel this proposed schedule on December 13 and have received no response.

Exchange of reply expert reports	Oct 8, 2025
Expert discovery deadline, including depositions	Nov 21, 2025
Deadline to Request Leave to File Summary Judgment	TBD
Submission of Opening *Daubert* Motions	TBD
Submission of Oppositions to *Daubert* Motions	TBD
Submission of Replies to *Daubert* Motions	TBD
Joint Final Pretrial Order deadline	No later than Feb 2026
Final Pretrial Conference	No later than Feb 2026
Trial	No later than Mar 2026 (or such date as the Court sets sufficient to account for post-trial filings and render an Opinion prior to the expiration of the 30-month stay)

To be clear, due to the potential delay that consolidation of all the ANDA actions, including recently filed actions where no answer has even yet been filed, could cause, Amneal opposes consolidation unless the consolidated action maintains deadlines sufficient for the Court to decide the merits prior to the expiration of the 30-month stay.

Conclusion

Should the Court determine that consolidation of the pending actions is appropriate, a case schedule should be set that prevents any undue prejudice to Amneal and permits a decision on the merits prior to the expiration of the 30-month stay in this case.

Dated: December 23, 2024

Jake M. Holdreith
(jholdreith@robinskaplan.com)
Christopher A. Pinahs
(cpinahs@robinskaplan.com)
Samuel J. LaRoque, Ph.D.
(slaroque@robinskaplan.com)
ROBINS KAPLAN LLP
800 LaSalle Ave, Suite 2800
Minneapolis, MN 55402
Tel.: (612) 349-8500

Oren D. Langer
(olanger@robinskaplan.com)
ROBINS KAPLAN LLP
1325 Avenue of the Americas, Suite 2601
New York, NY 10019
Tel.: (212) 980-7400

/s/ Rebekah Conroy
Rebekah Conroy (rconroy@stoneconroy.com)
STONE CONROY LLC
25 A Hanover Road, Suite 301
Florham Park, NJ 07932
Tel.: (973) 400-4181

Attorneys for Defendants Amneal Pharmaceuticals of New York, LLC and Amneal EU, Limited